DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 21, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-31

Blanca V. Madison, President
Scientific Botanicals Co., Inc.
P.O. Box 31131
Seattle, Washington 98103-1131

WARNING LETTER

Dear Ms. Madison:

The Food and Drug Administration (FDA) inspected your firm located at 8003 Roosevelt Way Northeast, Seattle, Washington, on January 27, 28, 29, and February 2, 2004. During that inspection we collected a sample of your dietary supplement product, Hydroxy Folate, and labels for your dietary supplement products Hydroxy Folate, Deglycyrrhizinated Licorice D.G.L., and Quercetin. Our analysis of Hydroxy Folate and review of your product labels indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the food and dietary supplement labeling regulations on the Internet through links on FDA's web page at www.fda.gov.

Our analysis of Hydroxy Folate revealed that the actual level of Folic Acid in the product is significantly less than the level listed on the label. The product is labeled to contain 400 mcg or 100% of the Reference Daily Intake per two drops. However, FDA analysis found that it contained less than 55% of the amount declared on the label. This causes Hydroxy Folate to be adulterated within the meaning of Section 402(b)(1) of the Act in that a valuable constituent, Folic Acid, has been in part omitted. Your product Hydroxy Folate is also misbranded under Section 403(a)(1) of the Act because the product labeling is false and misleading in that it states that it contains 400 mcg Folic Acid per serving when it in fact does not.

Hydroxy Folate, Deglycyrrhizinated Licorice D.G.L., and Quercetin are misbranded under sections 403(i)(1) and 403(s)(2)(B) of the Act in that their labels fail to identify the products using the term "dietary supplement," or a variation of the term using the name of the dietary ingredient as described in 21 CFR 101.3(g).

Furthermore, Hydroxy Folate, Deglycyrrhizinated Licorice D.G.L., Quercetin are misbranded under section 403(q)(5)(F) of the Act in that their labels fail to bear nutrition labeling ("Supplement Facts" panel) which is required under 21 CFR 101.36, and are not exempt.

The above violations are not an all-inclusive list of deficiencies in your facility or with your products. It is your responsibility to assure that all of your products and labels are in compliance with the Act and its implementing regulations. You should take prompt action to correct these deviations and prevent future recurrence. Failure to correct these violations promptly may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. Copies of revised labels should also be submitted. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state the time at which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Celeste M. Corcoran

for Charles M. Breen
District Director

cc: WSDA with disclosure statement